

## REMARKS

The issues outstanding in the office action mailed July 28, 2006, are the objections to the claims and the rejections under 35 U.S.C. §§§112, 102 and 103. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

### Claim Objections

The examiner's attention to detail is appreciated. Minor grammatical and typographical changes have been made to the claims, and withdrawal of these objections is respectfully requested.

### Rejections under 35 U.S.C. §112

Claim 2 has been rejected under 35 U.S.C. §112, second paragraph. The applicants respectfully disagree that one of ordinary skill in this art would not understand the meaning of "small proportion" of an organic solvent, the claim has been clarified in order to eliminate the rejection. Withdrawal of thereof is respectfully requested.

### Rejection under 35 U.S.C. §102

Claims 1-3, 5 and 7-8 have been rejected under 35 U.S.C. §102(b) over Anderson et al. (US 5,571,216). Reconsideration of this rejection is respectfully requested.

Anderson addresses a method of permanently joining a first collagen-containing material to a second collagen-containing material, each material having free ends of collagen fibrils at the surface of the first and second materials into contact, heating the first and second materials into contact, and heating the first and second materials for a time to a temperature sufficient to permanently join the first and second materials at an area of contact of the free ends. See the abstract. Thus, it is apparent that the target to be heated is the contact area between the first and second materials, not the overall material. This is because, as patentees explain, the joining or welding of collagen-containing materials should be performed "in novel ways that produce high welding strength and limit any damage, e.g., tissue denaturation, to an extremely narrow region a the weld seam" formed between the two materials. See, column 2, lines 16-22. To this end, Anderson employs a needle heating device or a wedge-like device, e.g., a plurality of needles 20 arranged in two rows heated

with a fluid, e.g., water, preheated to the desired temperature, to transfer heat to the weld seam region of the materials. See, column 5, lines 26-26. Similarly, a preheated fluid is circulated through the probe 25 of the wedge-like device. Water is not used as a bath in which tissue materials are immersed; the entirety of the material is not heated in the patent.

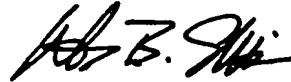
Although Anderson refers to microwave heating (column 6, line 2), it does not disclose how the two materials are heated exclusively at the contact area between them using the microwave heating, particularly heating the tissue material in a water bath. As is well-known, microwaves, as opposed to lasers, are not uni-directional and thus not suitable for limiting the heating to an extremely narrow region. If the tissue material is immersed in water or other treating solutions and then irradiated with microwaves, the material would be denatured or "cooked" because of elevated temperature of the liquid medium. Indeed, although the office action refers to column 6, line 1-6 and column 8, line 37 for "immersing the tissue in a welding bath." a careful reading of these portions of the reference- as well as the reference in its entirety- does not reveal such "immersion." The passage at column 8, lines 28-43 relates to the preparation of a specimen for testing for both tensile and weld strengths. In this example, sample discs are placed between sealed microscope cover slides clamped gently together and immersed in a circulating water bath. Since the sample discs are placed between sealed microscope cover plates, they are not exposed to a liquid medium for decellularization. In conclusion, neither claim 1, as amended, nor new independent claim 10, are anticipated or rendered obvious over Anderson.

Claim 4, 6 and 9 were rejected under 35 U.S.C. §103 as being obvious over Anderson and further in view of Kearns et al. or Boyce et al. However, the primary reference fails to disclose the method of claim 1 and this deficiency is not remedied by the secondary references. Accordingly, withdrawal of this rejection is also respectfully requested.

The claims in the application are submitted to be in condition for allowance. Should the examiner have any questions or comments, she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Harry B. Shubin, Reg. No. 32,004  
Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
Arlington Courthouse Plaza 1  
2200 Clarendon Boulevard, Suite 1400  
Arlington, VA 22201  
Telephone: 703-243-6333  
Facsimile: 703-243-6410  
Attorney Docket No.:AKA-0286

Date: October 30, 2006

HBS/blb

K:\AKA\286\REPLY 10-30-06.doc